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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,041	12/26/2001	Luc Desnoyers	P3030R1C8	4333

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,041	DESNOYERS ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-29 and 32-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32* is/are allowed.

6)☒ Claim(s) *22-29 and 33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment in paper No. 9, filed on 24 June 2003 is acknowledged and entered. Following the amendment, claims 22-29, 32, 33, 35 and 36 are amended, and claims 30 and 31 are canceled.

Currently, claims 22-29 and 32-41 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 30 and 31 are moot as the applicant has canceled the claims.

All objections and rejections of claims 22-29 and 32-34, 36, and 38-41 are withdrawn in view of applicant's amendments.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 37 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a nucleic acid of SEQ ID NO:1, and a nucleic acid encoding a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for claims to hybridization variants thereof (claim 35, for example), and fragments of hybridization variants (claim 37, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons set forth in the last Office Action, paper No. 8, mailed on 20 March 2003, at pages 4-6, and for the reasons below.

Applicants argument, filed on 24 June 2003 (paper No. 9) has been fully considered, but is not deemed persuasive for reasons below.

At page 16 of the response, applicants argue that regarding claim 35, the specification describes hybridization conditions and methodology, and that claim 35 has been amended to recite the functional limitation. This argument is not persuasive because the functional limitation is added to the nucleic acid sequence to which the claimed nucleic acid hybridizes, but not to the claimed nucleic acid. The claim, as written, does not require the *claimed* nucleic acid to have any functional property, such as encoding a polypeptide having the ability to induce chondrocyte redifferentiation. Further, even if the functional limitation were added to the claimed nucleic acid, the invention is still not commensurate in scope with the claim because the claim merely recites "hybridizes to" without specifying under what condition the nucleic acid hybridizes to the cited nucleic acid sequence. Such broad claim limitation reads on nucleic acids hybridize under any condition, and such nucleic acids would encompass nucleic acids encoding a functional equivalent of SEQ ID NO:2, i.e., the nucleic acid molecules that share some sequence homology to that encoding SEQ ID NO:2 (enough homology to "hybridize to"), and has the same functional property as that in the claim, yet are distinct molecules with other distinct functional properties from that of SEQ ID NO:2. The specification provides no guidance as to the structural and functional relationship of the molecule, nor working examples of any of such variants, which would be within the limitations of the claims. Therefore, it is unpredictable as to what hybridization variant would be within the claimed genus. Testing all variants under such a broad scope (hybridizing under any condition) without any predictability constitutes undue experimentation.

With respect to claim 37, applicants argue, at page 17 of the response, that the claim is enabled because one of ordinary skill in the art can easily make and use the recited nucleic acid sequences, and that the specification discusses various types of uses for nucleic acid fragments, such as probes, primers and antisense and sense nucleotides. This argument is not persuasive because, the issue is not how to make the fragments, rather, the issue is the scope of the claim encompasses small fragments (10 nucleotides) of the *hybridization variants* of claim 35, and such small fragments may not have any sequence similarity to the specific sequences in claim 35, parts (a)-(f). Such fragments would not be useful as a probe, primer or antisense nucleotide because they would not be able to bind to the target sequences as those in the claim 35. The specification provides no instruction, guidance, or working example regarding such fragments.

Therefore, one of skill in the art would not know how to use such a fragment, it would require undue experimentation to practice the invention in a manner commensurate in scope with the claims.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22-29 and 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Piddington et al., US 6,521,233 B1.

Piddington discloses a nucleic acid having SEQ ID NO:1 (1696 nucleotides), which comprises nucleotides 9-1704 of the instant SEQ ID NO:1 (1712 nucleotides) with 100% sequence identity, and encodes a human polypeptide, zacrp3, having an amino acid sequence of SEQ ID NO:2 (see computer printout of the search results). Piddington's polypeptide of SEQ ID NO:2 is 100% identical to SEQ ID NO:2 of the instant invention (see computer printout of the search results). Additionally, Piddington teaches a polynucleotide encoding the polypeptide of SEQ ID NO:2 lacking its signal peptide (column 3, lines 47-56). The reference, therefore, anticipates claims 22-29 and 33-37. With respect to the functional limitation in the claims, as the prior art amino acid sequence is 100% identical to that of the instant SEQ ID NO:2, the functional property is inherent. Further, Piddington teaches a vector comprising said nucleic acid, wherein the nucleic acid is linked to control sequences (column 4, line 66 to column 5, lines 3), and a host cell comprising the vector, wherein the host cell can be a CHO cell, an *E.coli*, or a yeast cell (column 24, lines 31 and 51-52, column 26, lines 32-33, and column 27, lines 31-33), thus, the reference also anticipates claims 38-41.

Conclusion:

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
8/4/03